

## **REMARKS**

Applicants would like to acknowledge, with appreciation, the Examiner's ongoing effort associated with prosecution of this application. The Office Action dated December 28, 2007 has been carefully reviewed. Applicants request reconsideration of this application in light of the amendments and remarks presented herein.

### **§103 REJECTIONS – DEVANATHAN/MCKELLOP**

Claims 49, 50, 52, 55, 125-129, and 132 were rejected under 35 U.S.C. §103 as being unpatentable over U.S. Patent No. 5,645,594 to Devanathan et al. (hereinafter "Devanathan") in view of U.S. Patent No. 6,165,220 to McKellop et al (hereinafter "McKellop"). Reconsideration of this application is respectfully requested.

In the 1/4/07 Office Action, the Examiner indicated:

"...it would have been obvious to one of ordinary skill in the art at the time the invention was made to have irradiated the articulating surface of the Devanathan et al. bearing with e-beam irradiation, as taught by McKellop et al., to produce cross-linking on its articulating surface for wear resistance."

In other words, the Examiner proposes to take Devanathan's molded, finished composite bearing and subject it to e-beam irradiation, as taught by McKellop.

As previously established on the record of this prosecution by both the Examiner and the Applicants, if one were to utilize surface-gradient crosslinking, as taught by McKellop, to crosslink the composite bearing of Devanathan, one of two results would be obtained based upon the dosage level of the radiation. In particular, if relatively low penetrating doses are used, the crosslinked/non-crosslinked (or /lesser crosslinked) gradient interface created by McKellop's technique would be contained in Devanathan's UHMWPE bearing layer (i.e., what is referred to as zone 1 or layer 12, 12' of Devanathan). On the other hand, if deeper penetrating doses are used, the crosslinked/non-crosslinked (or /lesser crosslinked) gradient interface created by McKellop's technique would extend beyond the UHMWPE bearing layer 12, 12' and be located in either

Devanathan's PMMA/UHMWPE layer 14, 14' or PMMA layer 16. As will be discussed below in greater detail, in either scenario, the proposed combination does not render the claims of the present application obvious.

### **I. The Use of Low Penetrating Doses Would Not Arrive at Applicants' Invention**

A combination of Devanathan and McKellop in which a relatively low penetrating dose is used to contain the crosslinked/non-crosslinked (or /lesser crosslinked) gradient interface created by McKellop's technique within Devanathan's outer bearing layer 12, 12' does not arrive at the invention of independent claims 49 and 125. Namely, the combination does not teach fusing non-crosslinked polyethylene to crosslinked polyethylene at a melt-fuse interface, nor does it teach fusing polyethylene crosslinked to a one degree to polyethylene fused to another degree at a melt-fuse interface. Specifically, it readily follows that if the crosslinked/non-crosslinked (or lesser crosslinked) gradient interface created by McKellop's technique is contained within Devanathan's layer 12, 12', then such a gradient cannot be interpreted to exist along a melt-fused interface since such a melt-fused interface occurs deeper within the bulk of Devanathan's implant (i.e., at the interface of the layers 12 and 14 or 12' and 14').

In short, any combination of Devanathan and McKellop that relies on the entirety of the gradient interface created by McKellop's technique to be contained within Devanathan's layer 12, 12' produces a bearing that fails to read on Applicants' independent claims since non-crosslinked polyethylene would not be melt-fused to crosslinked polyethylene at the melt-fused interface (as in claim 49), nor would polyethylene crosslinked to one degree be melt-fused to polyethylene crosslinked to another degree at the melt-fused interface (as in claim 125).

### **II. The Use of Higher Penetrating Doses Would Destroy Devanathan's Invention**

In a recent decision, the United States Supreme Court clarified the test for obviousness. See *KSR Int'l. Co. v. Teleflex, Inc. et al.*, 127 S.Ct. 1727 (2007). This decision has been codified for use by patent examiners throughout MPEP 2100. One fundamental principle

confirmed by the Supreme Court in KSR is that no proper analysis can support a finding of obviousness when the prior art actually teaches away from the proposed combination. The KSR Court emphasized the “principle that when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious.” KSR, 127 S.Ct. at 1740 (citing U.S. v. Adams, 383 U.S. 39, 51-52 (1966)). According to the Federal Circuit, the prior art effectively teaches away when an examiner’s proposed modification of the prior art renders the prior art invention “inoperable for its intended purpose.” In re Gordon, 733 F.2d 900, 902 (Fed. Cir. 1984). As will be discussed below in greater detail, Devanathan clearly teaches away from any combination or modification which causes crosslinking of its underlying PMMA layer(s) 14, 16.

As previously established on the record, the intent of Devanathan’s invention is to introduce PMMA into the implant to produce a bearing having increased stiffness and creep resistance. With this in mind, Applicants’ have argued that no one skilled in the art would utilize McKellop’s surface-gradient crosslinking technique in a manner that causes crosslinking of the PMMA-containing layers of Devanathan’s implant since to do so would destroy the intent of Devanathan’s invention. In particular, no one skilled in the art would utilize surface-gradient crosslinking to crosslink Devanathan’s bearing layer (i.e., layer 12) all the way down to the melt-fused interface since to do so would, *ipso facto*, require a significant portion of the underlying layer(s) of the implant beyond the melt-fused interface to likewise be crosslinked. This is true since the dosage required to produce crosslinking at the melt-fused interface would cause crosslinking, perhaps substantial crosslinking, to occur in the implant at a depth beyond the melt-fused interface and into the portion of the implant containing PMMA (i.e., Devanathan’s layers 14/14’ or 16). Realizing that PMMA was added to Devanathan’s implant to increase its creep resistance (see Devanathan at column 2, lines 37-45) and also realizing that it is known that crosslinking can lead to a reduction in creep resistance of PMMA, Applicants argue that no one skilled in the art would crosslink the PMMA-containing layer of Devanathan’s implant. To do so would be self-defeating. Namely, Applicants argue that no one skilled in the art would add material (i.e., PMMA) the

underlying layer of the implant to increase its creep resistance only to then subsequently subject the same underlying layer of the implant to a process (i.e., crosslinking) which is known to reduce creep resistance.

In response to this line of reasoning, the Examiner indicated that he “cannot find any evidence that some cross-linking of PMMA would negatively impact the creep properties of polyethylene.” Presumably the Examiner intended that he could not find evidence that crosslinking PMMA negatively impacts the creep resistance of PMMA (not polyethylene) since, as pointed out in the Background of the present application, it is well-known that crosslinking UHMWPE reduces its creep resistance. With this in mind, Applicants have filed herewith an IDS including an article entitled “Deformation of Poly(methyl methacrylate) after Exposure to Radiation and Magnetic Fields by Peschanskaya et al. (hereinafter “Peschanskaya”) that establishes that the creep resistance of PMMA is likewise reduced when it is subjected to radiation (see, amongst other locations, FIG. 4 of Peschanskaya and its associated discussion). *In other words, the prosecution record now makes it clear that the creep resistance of both UHMWPE and PMMA is reduced when either material is irradiated. With this in mind, Applicants maintain their position that one skilled in the art would not be motivated to irradiate Devanathan’s implant since doing so would lead to a reduction in its creep resistance thereby destroying the very intent of Devanathan’s invention of a bearing having increased creep resistance. To add a material (i.e., PMMA) to an implant to increase its creep resistance only to then subsequently subject the same material to a process (i.e., crosslinking) that is known to reduce creep resistance simply belies common sense.* At the end of the analysis, Devanathan simply teaches away from any process that reduces its creep resistance since a reduction in its creep resistance destroys the intent of Devanathan’s invention.

### **III. Conclusion Regarding the Section 103 Rejections Based on Devanathan and McKellop**

In short, the only combination of Devanathan and McKellop (to the extent they are even properly combinable) that doesn’t destroy the intended purpose of Devanathan (i.e., to produce a bearing with increased creep resistance) necessitates that the entirety of the gradient crosslinking

be confined to the polyethylene bearing layer 12, 12' of Devanathan. To do so produces a bearing that fails to read on Applicants' claims since non-crosslinked polyethylene would not be melt-fused to crosslinked polyethylene at the melt-fused interface (as in claim 49), nor would polyethylene crosslinked to one degree be melt-fused to polyethylene crosslinked to another degree at the melt-fused interface (as in claim 125).

## CONCLUSION

In view of the foregoing, it is submitted that this application is in a condition for allowance. Action to that end is hereby solicited.

It is respectfully requested that, if necessary to effect a timely response, this paper be considered as a Petition for an Extension of Time sufficient to effect a timely response and shortages in other fees be charged, or any overpayment in fees be credited, to the Account of Barnes & Thornburg, Deposit Account No. 10-0435 with reference to file 265280-68002.

Respectfully submitted,

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